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(54) Peritoneal dialysis equipment

(57) In peritoneal dialysis equipment a spike 14 for detachably connecting one part of the equipment to another has a removable cover 8, 9, 10 which is axially compressible. The inner surface of the cover 8, 9, 10 contacts the spike 14 and can retain sterilising medium. A tubular non-compressible separable axial extension of the cover may be provided as a handle. When the spike 14 is inserted into e.g. a bag of dialysis liquid the handle is removed and the cover 8, 9, 10 is compressed. Fitting, removing, compression, and expansion of the cover 8, 9, 10 all cause the inner surface to wipe the spike 14 and act to sterilise it. This reduces the risk of infection associated with the use of such equipment.

Fig.3.

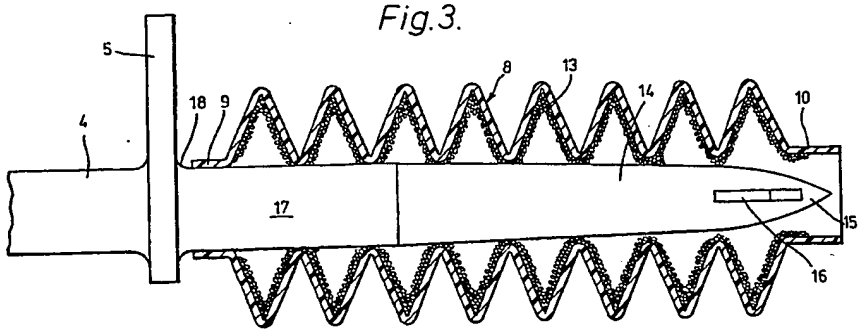

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Fig.1.

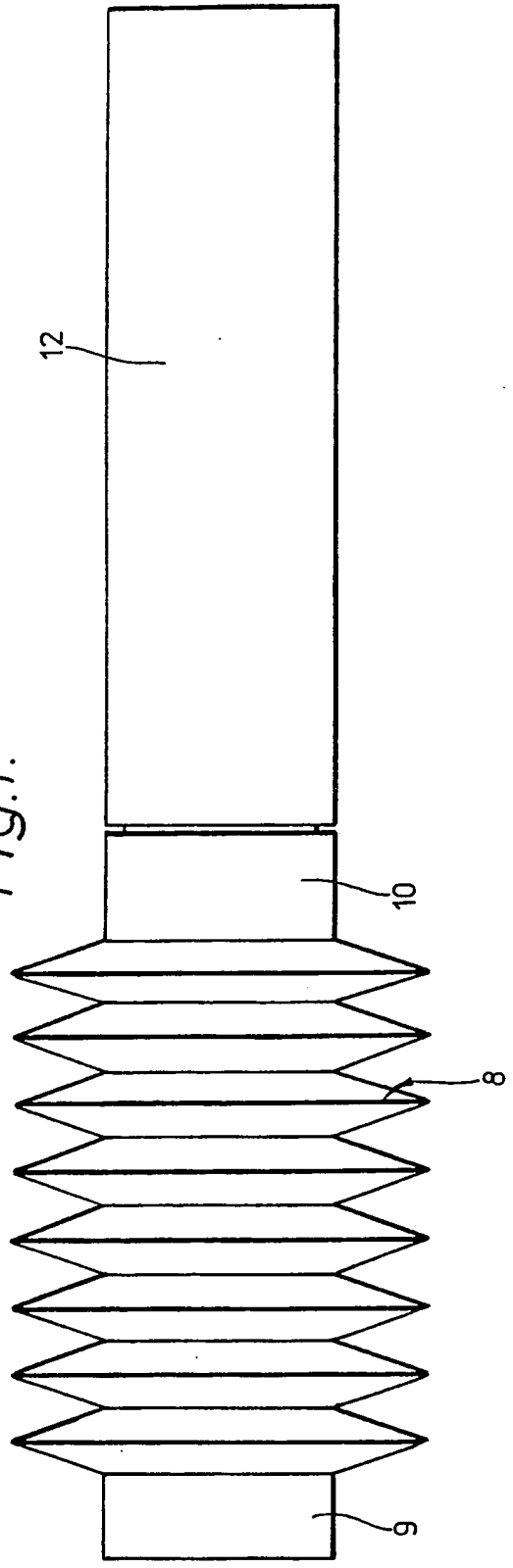
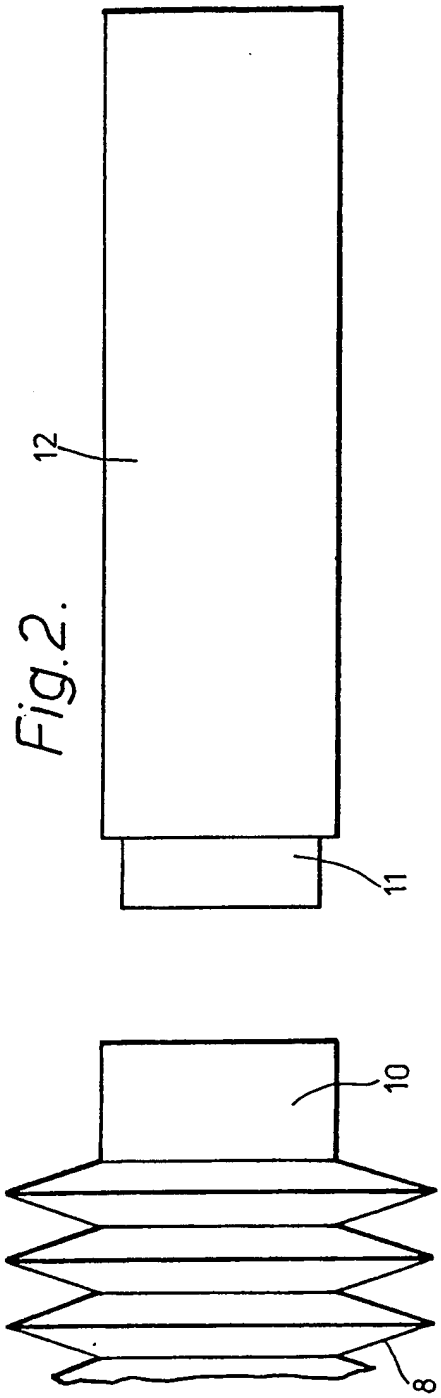


Fig.2.



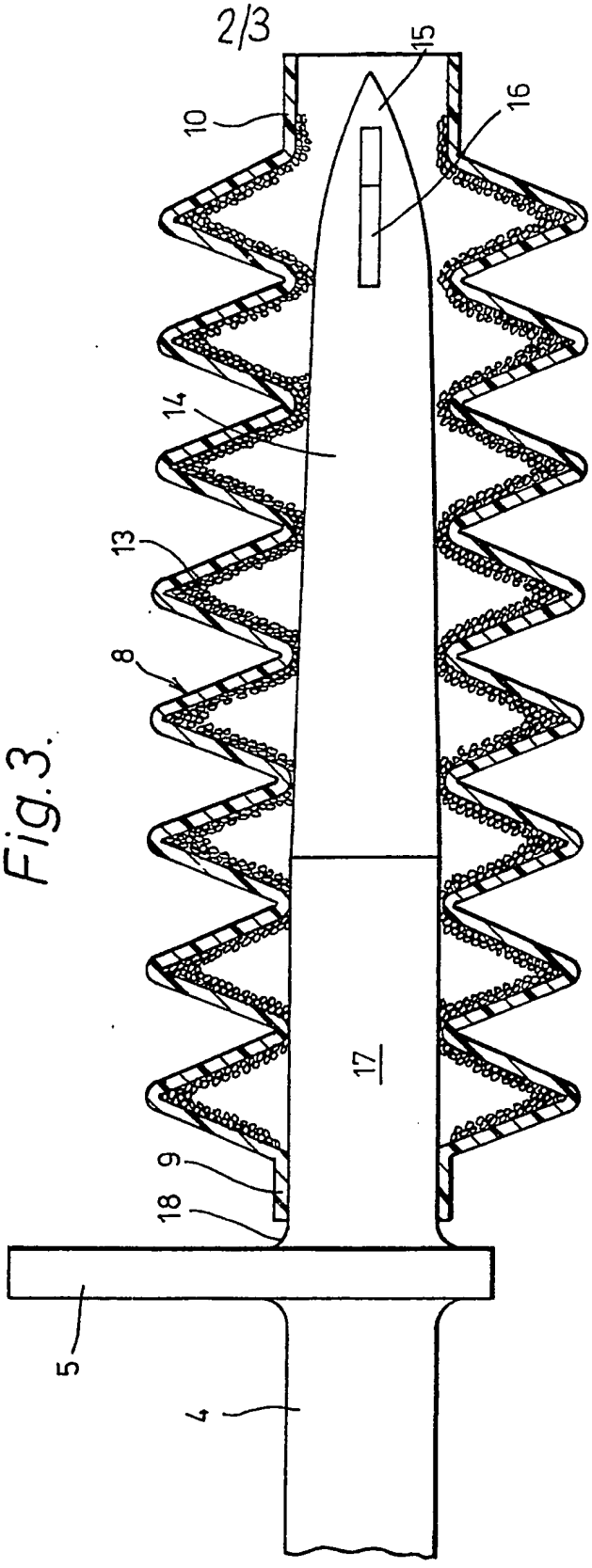


Fig.3.

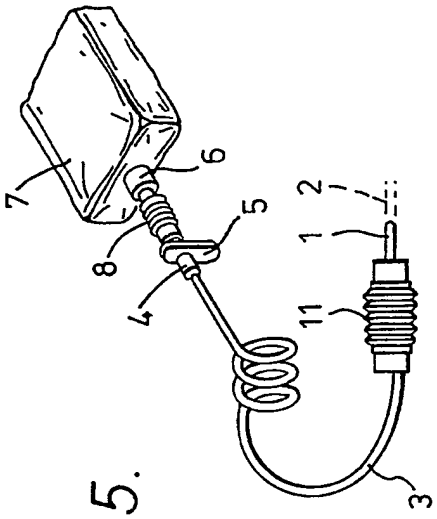


Fig.5.

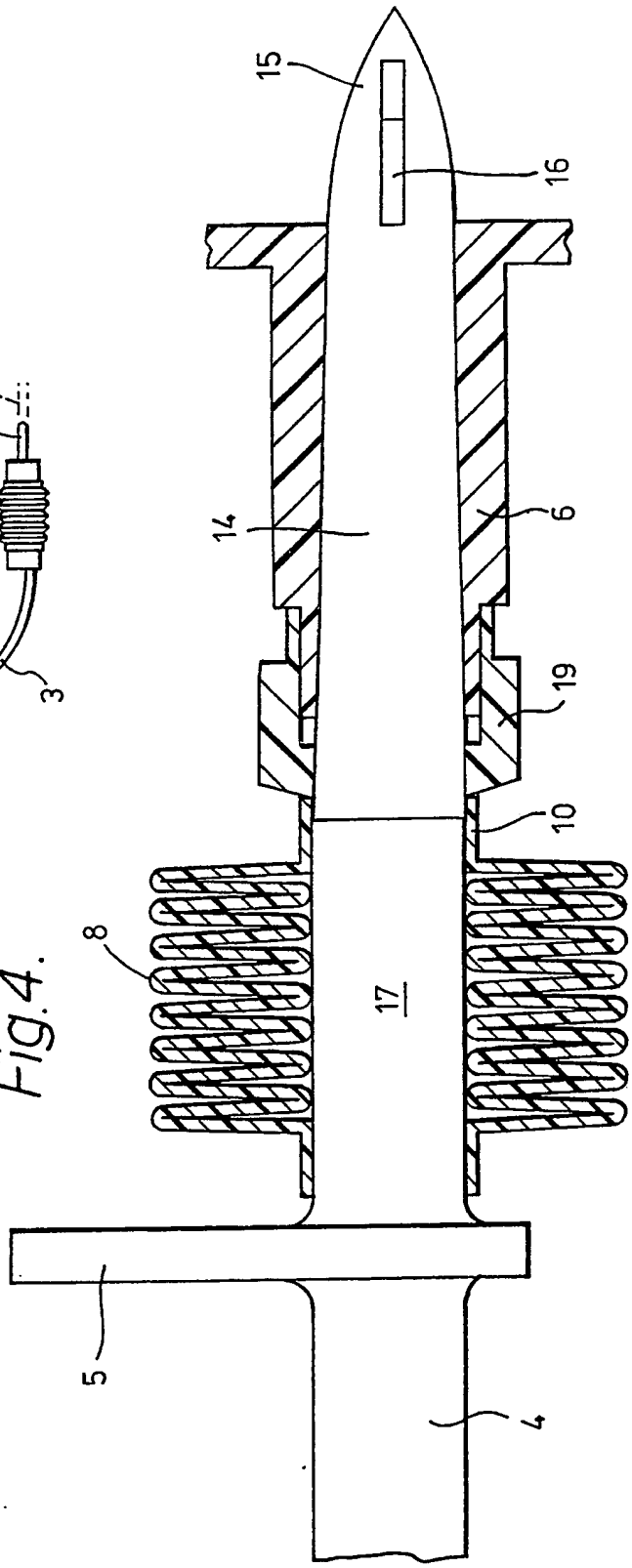


Fig.4.

SPECIFICATION

Peritoneal dialysis equipment

This invention relates to the equipment used in peritoneal dialysis and is concerned with the connectors which are used in that equipment.

For peritoneal dialysis an incision is made in the abdominal wall and a catheter is inserted semi-permanently through it so that its inner end is within the enclosure formed by the peritoneal membrane. The catheter projects outside the abdominal wall and there is connected to a long flexible tube which is known as the giving tube.

The treatment consists in applying through the giving tube from a sterile bag a quantity, which varies according to the patient but is usually between one and two litres, of a carefully formulated and sterilised fluid. This perfuses the region within the peritoneal membrane and there is osmosis through the peritoneal membrane. After a given period which will depend on the precise nature of the treatment the fluid is withdrawn through the catheter and the giving tube and disposed of, and a fresh quantity of fluid is fed in.

The exact nature of the treatment will depend on whether the treatment is being performed in a hospital or other special centre (in which case the fluids are being inserted and withdrawn mechanically by machine while the patient remains inactive) or whether it is a process known as continuous ambulatory peritoneal dialysis (CAPD) where the patient himself connects the filled bag and after the treatment drains the liquid as necessary. The latter is of course a preferable treatment from the point of view of the mobility of the patient, of the low equipment and overhead costs and of the fact that no skilled medical staff are necessary.

However both these procedures depend on the connection and disconnection of the catheter and/or the giving tube to the fluid bags involved or the machine involved.

The abdominal cavity within the peritoneal membrane is particularly susceptible to infection and it is of the utmost importance that sterility should be preserved in these connections. Although this is less of a problem in the hospital where skilled staff are available the difficulties and dangers facing the patient undergoing a CAPD regime are obvious.

The usual procedure in CAPD is this:–

When the bag full of fluid has been emptied through the giving tube and catheter into the abdominal cavity then that bag is taken off a needle-like element on the end of the giving tube which is known as a spike and a new and empty bag is fitted onto that spike. The new bag is worn by the patient under his clothing until it comes to be time for drainage. At that time the empty bag is used to receive the used fluid, the spike is removed from that bag and inserted into the next one to be used which is full of the sterile and new fluid.

Although some procedures are different, whatever procedure is used there will be one disconnection and one connection to be made every time the treatment is repeated.

All staff and all patients are warned of the dangers of infection which in these circumstances are primarily contact infections rather than airborne infections. Patients at home are taught to maintain the spike while it is exposed between disconnection and connection within a wad of gauze which is steeped in a sterilising material such as "Hibitane" (RTM).

However this is a slightly makeshift arrangement and there remain serious dangers of the patient touching the spike, particularly at the time when the introduction of the spike into the new bag is just about to begin. It there is an accidental touching or dropping of the spike there is a complicated procedure for trying to ward off the damage which might be done, which involves in most cases fitting a complete new giving tube.

The present invention is concerned to provide a much more reliable means of preserving the cleanliness of a spike of peritoneal dialysis equipment in a much more mechanical and reliable way and one which is almost completely independent of the skill and manual dexterity of the patient or operator.

The present invention is peritoneal dialysis equipment having a tubular cover member over a spike, the cover member on its inner surface being capable of retaining a sterilising medium and being axially compressible. It is particularly advantageous to associate this compressible element with a further non-compressible one which is readily separable from it and which forms an axial extension of it. This further element is also hollow and acts as a handle.

Holding the handle the patient can feed the cover over the end of the exposed spike and in doing so he will wipe the surface of the spike against the internal surface of the cover member. The handle remains free of the spike because the natural length of the compressible sleeve is greater than the length of the spike. Then the handle is broken off leaving the spike covered. Of course the spike is not hermetically sealed by the cover but it is protected from anything but deliberate contact involving compression of the cover.

Then the spike may be held by its normal handle which is in a region remote from any where there could be transfer of organisms into the stream of fluid, and is inserted into the bag. During this action the collapsible cover is axially collapsed by being pressed against the bag and in doing so once again wipes the surface of the spike. It then remains in its axially compressed state on the portion of the spike which is not inserted into the bag and forms a sterile cover for that. When the bag is disconnected the cover expands once more (wiping the surface of the spike which may have been exposed to the used fluid) and at this stage the spike may then be inserted once more in a new bag without changing the cover. It is preferable to replace the cover however at this stage removing the old one and replacing it by a new one newly bathed in sterlising medium.

The form of the cover is preferably that of a bellows formed of a flexible plastics material which has an inner lining of a medical gauze which is moulded to the interior surface of the bellows during the manufacture of the latter. The natural length of the

bellows is as stated slightly longer than the length of the spike; the total length of the combination of bellows plus handle is such that when the bellows is fully compressed the length of the combination is slightly greater than the length of the spike.

A particular embodiment of the invention will now be described with reference to the accompanying drawings wherein:

Fig. 1 is a side elevation of the embodiment including a handle fitted to the compressible cover,

Fig. 2 shows the handle detached,

Fig. 3 is a longitudinal section through the compressible cover fitted on a spike

Fig. 4 is a longitudinal section showing the spike fitted to a bag and the cover in compressed condition and

Fig. 5 is a sketch of the complete equipment with a bag fitted.

Referring first to Fig. 5, there is shown a catheter 1 of which part 2 penetrates the abdominal wall and the peritoneal membrane. Its end exposed outside the abdomen is coupled for example by a Luer fitting to a long, flexible giving tube 3 on the other end of which is permanently welded a boss 4 with a handle 5 and projecting spike (not seen in this Figure) which pierces a septum in the neck 6 of a bag 7 so as to be placed in fluid communication with the inside of that bag. There can be seen compressed upon the base of the spike a bellows 8 which as will now be described in more detail forms a compressible cover for the spike.

Fig. 1 shows the compressible cover in its expanded and relaxed condition. It is in the form of a bellows 8 made e.g. by dip moulding, of a suitable medical grade plastics material. It has cylindrical sleeve ends 9 and 10 which are identical and which are of an internal diameter to form a steady fit with a base portion of the spike, as will be explained. Inside the sleeve 10 there can be fitted an extension 11 of a rigid hollow sleeve 12 of which the main portion has the same outside diameter as the sleeve 10. The extension 11 forms a strong interference fit within the sleeve 10 so that for normal purposes when the handle 12 and the bellows 8 are forced together as seen in Fig. 1 they can be considered as a unit.

Before use, this unit is immersed in a bath of sterilising liquid such as Hibitane (Registered Trade Mark). As can be seen from the section in Fig. 3 the inner surface of the bellows 8 is lined with a liquid absorbent material 13. This is suitably a medical gauze. This may be a separate sleeve of absorbent material loosely fitted or adhered within the bellows but is much more preferably a layer moulded in situ with the bellows so as to be strongly retained by the plastics material.

When the combined handle 12 and cover is in the sterilising liquid not only therefore is this sterilising surfaces of the combination but a certain amount of sterlising liquid will be taken up in the gauze.

The minimum diameter of the plastics portion of the folds of the bellows 8 is the same as the internal diameter of the end portions 9 and 10.

The boss 4 at the end of the giving tube and the manipulating handle 5 are fast with a spike 14 seen in Figs. 3 and 4 and the spike is of a generally tapering conformation towards a convexly curved but sharp end part 15 in which there is a port 16 leading to the hollow interior of the spike and hence to the giving tube 3. The base portion 17 of the spike nearest to the boss 4 is cylindrical, without taper but has a slight flare 18 at its root.

To explain the operation of the compressible cover, we will first assume the spike just to have been withdrawn from a bag 7 into which used fluid has been drained. At this stage the spike may have a cover on it in the condition seen in Fig. 3. This cover is taken off and discarded. A fresh cover is then picked up by its handle from the bath of sterilising material in which it was placed ready for use and is slipped over the needle in the axial direction until the sleeve 9 has come to the root of the base 17 where there is the slight flare 18. During this action the sterlising liquid retained on the surface of the cover and particularly by the absorbent layer 13 will wipe the surface of the spike 14 with fresh sterilising medium. When the sleeve 9 is in position the handle 12 is broken from the sleeve end 10 so that its extension 11 is withdrawn. The relaxed length of the cover from end 9 to end 10 is slightly greater than that of the spike 14 so that the end part 15 of the spike will not be accessible to touching except as a result of deliberate compression of the cover. The spike 14 is now taken, using the manipulating handle 5, and is inserted through the septum of a fresh bag 7, passing into the neck portion 6 of the bag which may have an internal fitting taper. The port 16 is now in communication with the interior of the bag and fluids can therefore be passed from the bag down the giving tube. However the act of inserting the spike into the bag has involved compression of the bellows onto the base 17 of the spike, the end 10 having been acted on by the cap 19 of the neck of the bag. This compression has again wiped the surface of the spike on the absorbent surface, and the cover remains on the base 17 of the spike preventing it being touched and in its compressed condition will tend to retain and prevent evaporation or contamination of the sterilizing material held by it.

When that bag is finished with, it is taken off the spike. The cover now expands again as the cap 19 is withdraws with the bag, so that it once more reaches the condition seen in Fig. 3, during this action once more wiping the surface of the spike. The cycle is now ready to re-start with preferable replacement of that once-used cover with a new one from a freshly prepared bath of sterlising material.

It can be seen that at no stage is any part of the spike exposed to the touch of anything except the cover or the mouth parts of the bag, even though before the spike is inserted into the bag its end portion 15 is exposed to air through the end 10 of the cover.

Although the embodiment is shown as being a spike on the end of a giving tube for insertion in a bag, similar spikes are fitted to tubes to be connected to peritoneal dialysis machines and may be used there or in any other position in such equipment where it is useful.

CLAIMS

1. Peritoneal dialysis equipment including a

spike for connecting one part of the equipment to another surrounded by an axially compressible tubular cover, the inner surface of the cover being in contact with the spike and being capable of retaining a sterilising medium.

2. Peritoneal dialysis equipment according to claim 1 wherein the tubular cover is removable from the spike.

3. Peritoneal dialysis equipment according to claim 1 or claim 2 in which the cover, when not compressed, extends beyond the tip of the spike.

4. Peritoneal dialysis equipment according to claim 1 claim 2 or claim 3 in which there is associated with the cover a tubular non-compressible handle member co-axial with the cover and removably attached to the spike tip end of the cover.

5. Peritoneal dialysis equipment according to any one of the preceding claims in which the inner surface of the cover is formed of a gauze.

6. Peritoneal dialysis equipment according to claim 5 in which the gauze is integrally attached by moulding to the remainder of the cover.

7. Peritoneal dialysis equipment according to any one of the preceding claims in which the cover is of a bellows construction, the inner surface of the cover being in contact with the spike around the inner folds of the bellows.

8. Peritoneal dialysis equipment as described with reference to and as illustrated in the accompanying drawings.

9. A cover for peritoneal dialysis equipment according to any one of the preceding claims.

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